K010010 APR - 2 2001

SUMMARY OF SAFETY AND EFFECTIVENESS

Submitter Information:

Valleylab
5920 Longbow Drive
Boulder, Colorado 80301
(303) 530-2300
Contact person: Julie Ross
Senior Regulatory Associate
Prepared: 12/29/00

Name of the Device

Proprietary Name:
Valleylab LigaSure™ Precise Instrument Vessel Sealing System

Common or Usual Name:
Bipolar electrosurgical instrument and bipolar electrosurgical generator

Classification Name:
Class II, 21 CFR 878.4400, Electrosurgical Cutting and Coagulation Device and Accessories, Panel 79, General and Plastic Surgery.

Product Description

The Valleylab LigaSure™ Precise Instrument Vessel Sealing System consists of the following devices:

- LigaSure™ Vessel Sealing Generator (K981916)
- LigaSure™ Footswitches (Catalog number LS0010 and LS0020) (K981916)
- LigaSure™ Precise Instrument (Catalog number LS1200)

The Valleylab LigaSure™ Precise Instrument Vessel Sealing System utilizes an isolated, microprocessor based, bipolar electrosurgical generator which provides a vessel sealing mode. The vessel sealing process is controlled by an internal microprocessor and associated software within the generator. The control system senses the LigaSure™ Precise Instrument and initiates a predetermined RF energy cycle which fuses the tissue between the jaws to form the ligation (seal).

The generator also provides bipolar electrosurgical energy to accommodate standard bipolar cutting and coagulation instruments.

The LigaSure™ Precise Instrument is a single use device which is provided sterile. This device is similar to bipolar forceps in that the instrument has a scissors closing action with flat jaws in which vessels/tissues are grasped and through which pressure and bipolar energy are applied. It is a multifunctional device capable of vessel sealing, grasping and dissecting during open general surgical procedures. The Precise Instrument is a lightweight, precision instrument intended for access in confined areas such as the head and neck. The small jaws allow fine grasping of delicate tissues, effective tissue dissection, and minimal sticking of tissue. The tonsil or "mosquito" style jaws are smooth, with the addition of several ceramic "dots" which provide both atraumatic grasping for fine tissue manipulation and maintain a consistent gap between the electrode surfaces.

The design of the Precise instrument handle allows for both ring motion (with the thumb inserted into the thumb hole) and also palming, depending on user preference. The handle also includes a latching mechanism to maintain the applied pressure. Power is delivered to the instrument electrodes (jaws) by a two conductor cord contained within the handle. The cord of the instrument is 10 feet in length and terminates in a dedicated connector plug.

Product features:

- Vessel sealing creates a translucent seal, and provides a visual indication of seal integrity.
- Surgical ligation is confined to the target tissue, with minimal thermal spread to surrounding tissues.
- Average lateral thermal spread is less than 1 mm in isolated vessels ranging from 0-7 mm.
- Small jaws provide improved visibility of target tissue.

Intended Use

The Valleylab LigaSure™ Precise Instrument Vessel Sealing System includes a bipolar electrosurgical generator (legally marketed under K981916) and a dedicated bipolar electrosurgical instrument. The system is intended for use in general procedures where ligation of vessels is desired. This system creates ligation by the application of bipolar electrosurgical RF energy and pressure to vessels interposed between the jaws of the instrument.

The indications for use for the Valleylab LigaSure™ Precise Instrument Vessel Sealing System include general procedures (including urologic, thoracic, plastic and reconstructive) where ligation of vessels is performed, including such procedures as bowel resections, gall bladder procedures, Nissen fundoplication, adhesiolysis, etc. The instrument can be used on vessels up to 7mm and bundles as large as will fit in the jaws of the instrument.

The LigaSure Vessel Sealing System has not been shown to be effective for tubal sterilization or tubal coagulation for sterilization procedures. Do not use this system for these procedures.

Summary of Technological Characteristics

The Valleylab LigaSure™ Precise Instrument Vessel Sealing System consists of the legally marketed LigaSure™ Vessel Sealing Generator (K981916). The Valleylab LigaSure™ Precise Instrument is substantially equivalent in function and intended use to the following legally marketed devices:

- Valleylab LigaSure™ Standard Instrument LS2070 (K981916)
- Valleylab LigaSure™ Laparoscopic Instrument LS1000 (K981916)

Both predicate devices are used in general surgical procedures where ligation of vessels is performed.

Performance Data

Preclinical laboratory (acute and chronic studies) and performance testing were performed to ensure the Valleylab LigaSure™ Precise Instrument Vessel Sealing System functioned as intended and met design specifications. Sufficient data was obtained to show that the system was equivalent to the predicate devices and met safety and effectiveness criteria.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR - 2 2001

Ms. Julie Ross
Senior Regulatory Associate
Valleylab
5920 Longbow Drive
Boulder, Colorado 80301

Re: K010010
Trade Name: Valleylab LigaSure Precise Instrument Vessel
Regulatory Class: II
Product Code: GEI
Dated: December 29, 2000
Received: January 2, 2001

Dear Ms. Ross:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K010010

Device Name: **Valleylab LigaSure™ Precise Instrument Vessel Sealing System**

Indications For Use:

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Miriam C. Provost

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K010010

Prescription Use ✓ OR Over-The-Counter Use ___
(Per 21 CFR 801.109)

(Optional Format 1-2-96)